Complete Summary

GUIDELINE TITLE

Diagnosis and treatment of obstructive sleep apnea.

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 May. 53 p. [117 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Obstructive sleep apnea hypopnea syndrome (OSAHS)

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Dentistry
Family Practice
Internal Medicine
Neurology
Otolaryngology

Pulmonary Medicine
Sleep Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To increase the percentage of patients 18 and older who are diagnosed with obstructive sleep apnea hypopnea syndrome (OSAHS) through a sleep study evaluation
- To increase the percentage of patients with obstructive sleep apnea hypopnea syndrome who have received appropriate treatment according to guideline
- To increase the percentage of patients who have documentation of appropriate follow-up
- To increase patient understanding of the health risk factors related to obstructive sleep apnea hypopnea syndrome

TARGET POPULATION

Adult patients age 18 and older at risk for obstructive sleep apnea hypopnea syndrome (OSAHS)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination, including review of symptoms and co-morbid risk factors
2. Overnight oximetry
3. Sleep study, such as polysomnography or unattended in-home study
4. Determination of severity of obstructive sleep apnea using the three domains of sleepiness, respiratory disturbance, and gas exchange abnormalities

Treatment/Management

1. Lifestyle modification, such as weight loss; reduction of alcohol consumption,especially before bedtime; body position during sleep; good sleep hygiene; integration of positive air pressure (PAP) preparation into a bedtime routine and bedroom environment
2. Oral appliances, such as mandibular repositioning devices and tongue retaining devices

3. Positive airway pressure devices, such as continuous positive airway pressure (CPAP); self-titrating CPAP (AutoPAP); Bi-level PAP
4. Patient compliance efforts such as education and Alert Well and Keeping Energetic (AWAKE) meetings
5. Surgical procedures, such as septoplasty; nasal polypectomy; tonsillectomy; turbinoplasty; tracheostomy; uvulopalatopharyngoplasty (UPPP); radiofrequency ablation of the soft palate and tongue base; hyoid suspension; and mandibular advancement, genioglossus advancement, and/or maxillary advancement
6. Follow-up
7. Referral to specialists, such as sleep specialist or otolaryngologist

MAJOR OUTCOMES CONSIDERED

- Signs and symptoms of obstructive sleep apnea
- Patient risk factors, including co-morbidities
- Accuracy (sensitivity and specificity, positive and negative predictive value) of diagnostic tests
- Effects of treatment on apnea-hypopnea index and other measures of obstructive sleep apnea
- Patient compliance and patient satisfaction with treatment
- Complications of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Key conclusions (as determined by the work group) are supported by a conclusion grading worksheet that summarizes the important studies pertaining to the conclusion. Individual studies are classed according to the system presented below, and are designated as positive, negative, or neutral to reflect the study quality.

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results from different studies or because of serious doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

Study Quality Designations:

The quality of the primary research reports and systematic reviews are designated in the following ways on the conclusion grading worksheets:

Positive: indicates that the report or review has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

Negative: indicates that these issues (inclusion/exclusion, bias, generalizability, and data collection and analysis) have not been adequately addressed.

Neutral: indicates that the report or review is neither exceptionally strong nor exceptionally weak.

Not Applicable: indicates that the report is not a primary reference or a systematic review and therefore the quality has not been assessed.

Classes of Research Reports:

A. Primary Reports of New Data Collection:

    Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

- Cross-sectional study
- Case series
- Case report

B. Reports that Synthesize or Reflect upon Collections of Primary Reports:

Class M:

- Meta-analysis
- Systematic review
- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Published cost analyses were reviewed.

The overall costs and effectiveness of combined cardiorespiratory sleep testing followed by auto-titrating positive airway pressure (PAP) therapy, as compared to split-night polysomnography and continuous positive airway pressure (CPAP) therapy, has not been extensively characterized. Two analyses of differing strategies for diagnosis and treatment of obstructive sleep apnea hypopnea syndrome (OSAHS) found unattended polysomnography to have a superior cost-utility to home cardiorespiratory testing but did not compare strategies outlined in this guideline. Although not duplicative of the guideline recommendations, this analysis highlighted the importance that tests for OSAHS have very high sensitivity (>93%) in order to provide favorable cost-utility.

A nurse managed program combining a very low calorie diet with behavior management on an outpatient basis was found to be safe and cost-effective as a primary treatment for OSAHS.

METHOD OF GUIDELINE VALIDATION

Clinical Validation-Pilot Testing
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Institute Partners: System-Wide Review

The guideline draft, discussion, and measurement specification documents undergo thorough review. Written comments are solicited from clinical, measurement, and management experts from within the member medical groups during an eight-week period of "Critical Review."

Each of the Institute's participating medical groups determines its own process for distributing the guideline and obtaining feedback. Clinicians are asked to suggest modifications based on their understanding of the clinical literature coupled with their clinical expertise. Representatives from all departments involved in implementation and measurement review the guideline to determine its operational impact. Measurement specifications for selected measures are developed by the Institute for Clinical Systems Improvement (ICSI) in collaboration with participating medical groups following general implementation of the guideline. The specifications suggest approaches to operationalizing the measure.

Guideline Work Group: Second Draft

Following the completion of the "Critical Review" period, the guideline work group meets 1-2 times to review the input received. The original guideline is revised as necessary and a written response is prepared to address each of the suggestions

received from medical groups. Two members of the Respiratory Steering Committee carefully review the Critical Review input, the work group responses, and the revised draft of the guideline. They report to the entire committee their assessment of two questions: (1) Have the concerns of the medical groups been adequately addressed? (2) Are the medical groups willing and able to implement the guideline? The committee then either approves the guideline for pilot testing as submitted or negotiates changes with the work group representative present at the meeting.

Pilot Test

Medical groups introduce the guideline at pilot sites, providing training to the clinical staff and incorporating it into the organization's scheduling, computer, and other practice systems. Evaluation and assessment occur throughout the pilot test phase, which usually lasts for three months. Comments and suggestions are solicited in the same manner as used during the "Critical Review" phase.

The guideline work group meets to review the pilot sites' experiences and makes the necessary revisions to the guideline, and the Respiratory Steering Committee reviews the revised guideline and approves it for implementation.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations for the diagnosis and treatment of obstructive sleep apnea are presented in the form of two algorithms with 16 components, accompanied by detailed annotations. Algorithms are provided for Diagnosis of Obstructive Sleep Apnea and Sleep Apnea Treatment. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Class of evidence (A-D, M, R, X) ratings and key conclusion grades (I-III, Not Assignable) are defined at the end of the "Major Recommendations" field.

Clinical Highlights for Individual Clinicians

1. The following signs and symptoms may suggest significant risk for obstructive sleep apnea hypopnea syndrome (OSAHS) (Annotation #4):
    - Reported apneas by sleep partner
    - Awakening with choking
    - Intense snoring
    - Severe daytime sleepiness, especially with impairment of driving
    - Male gender
    - Obesity (body mass index [BMI] greater than or equal to 30)
    - Large neck circumference (greater than 16.5 inches in men)
    - Hypertension
2. OSAHS is a significant risk for the development of hypertension and perhaps also for poorly controlled diabetes which is worsening, coronary artery disease, and cerebrovascular disease, and may lead to significant impairments in quality of life. (Annotations #1, 3)

3. The accepted standard test for diagnosis of OSAHS is polysomnography, which is indicated for the diagnosis of all patients suspected of having this disorder. (Annotation #7)
4. All patients with a diagnosis of OSAHS should receive education and guidance in lifestyle modification. (Annotation #9)
5. Management of mild OSAHS may include one or more of the following treatment modalities: oral appliances, positive airway pressure devices, surgery. (Annotation #11)
6. Management of moderate to severe OSAHS includes the use of positive airway pressure devices. Patients who are intolerant of positive airway pressure devices, or those who are not adequately managed with positive airway pressure alone, may be considered for surgery. (Annotation #12)

Diagnostic Algorithm Annotations

1. Review of Symptoms Positive for Obesity, Hypertension, and/or Large Neck Circumference

   A thorough review of symptoms will include questions related to obstructive sleep apnea hypopnea syndrome (OSAHS). Physical exam will identify predisposing characteristics that should lead to further in-depth investigation of the possibility of OSAHS.

   The risk for OSAHS correlates on a continuum with obesity (high body mass index [BMI]), large neck circumference, and hypertension. Combinations of these factors increase risk for OSAHS in a non-linear manner.

   Evidence supporting this recommendation is of classes: B, D, R

2. Patient Presents to Provider for Routine Health Maintenance Exam

   During an exam the practitioner should be aware of physical exam findings that predispose patients to OSAHS:

   1. Large neck circumference
   2. Obesity (high BMI)
   3. Hypertension
   4. Specific abnormalities that could lead to upper airway obstruction

   Evidence supporting this recommendation is of classes: B, D, R

3. Patient Presents to Provider for Care of One or More of the Following Conditions: Cardiovascular Disease (CVD), Coronary Artery Disease (CAD), Hypertension (HTN), Obesity, Sleep Complaint

   OSAHS occurs frequently in patients who have been diagnosed with cerebrovascular disease (CVD), coronary artery disease (CAD), or in patients who present with complaints of disturbed sleep. OSAHS is a significant risk factor for the development of hypertension (HTN) and perhaps also for insulin resistant diabetes, coronary artery disease and cerebrovascular disease, and may lead to significant impairment in quality of life. Treatment of OSAHS may

improve ejection fraction and lower blood pressure in heart failure patients, decrease the recurrence of atrial fibrillation after cardioversion and lower daytime blood pressure in hypertensive patients. Obstructive sleep apnea may also elicit nocturnal bradyarrhythmias and nocturnal angina. Treatment of the obstructive sleep apnea may result in resolution of both of these problems. When patients present for evaluation or follow-up of specific complaints that have a high correlation with OSAHS, further investigation should occur.

Evidence supporting this recommendation is of classes: A, B, C, D, R

4. Signs and Symptoms Suspicious for OSAHS

The following signs and symptoms have been found by population studies employing logistic regression analysis to suggest significant risk for OSAHS:

1. Awakening with choking
2. Hypertension
3. Intense snoring
4. Large neck circumference
5. Male gender
6. Obesity
7. Reported apneas or choking by sleep partner
8. Resistant hypertension and/or atrial fibrillation
9. Atrial Fibrillation
10. Severe daytime sleepiness, especially with impairment of driving

In patients with a low clinical suspicion for OSAHS, overnight oximetry may assist in clinical decision-making. In evaluating daytime sleepiness it is important to rule out sleep deprivation (i.e., insomnia and poor sleep hygiene). Episodic awakening with choking can also be caused by gastroesophageal reflux disease.

[Conclusion Grade II: See Conclusion Grading Worksheet - Appendix A - Annotation #4 (Signs/Symptoms Suspicious for OSAHS) in the original guideline document]

Evidence supporting this recommendation is of classes: C, M

5. Atypical or Complicating Symptoms Present?

The following situations should prompt referral of a patient suspected of sleep apnea to a sleep specialist or other appropriate specialist, rather than following the obstructive sleep apnea hypopnea syndrome (OSAHS) protocol:

- Congestive heart failure, either stable or severe (New York Heart Association [NYHA] Class I-IV)
- Significant pulmonary disease, including:
    - Severe chronic obstructive pulmonary disease (COPD)
    - Baseline hypoxemia
    - Hypercapnia

    - Pulmonary hypertension
- Inability to tolerate testing or possible positive airway pressure (PAP) therapy
- Unusual sleep-related behaviors (parasomnias) or strong suspicions of sleep disorders other than OSAHS
- Significant neurological or neuromuscular disease, including but not limited to:
    - Myopathies
    - Amyotrophic lateral sclerosis (ALS)
    - Significant Parkinson's syndromes

Commercial drivers, pilots, or others requiring Department of Transportation, Federal Aviation Administration, or Department of Defense evaluations should be considered for referral to a sleep disorders center.

Evidence supporting this recommendation is of classes: C, D, R

6. Refer to Sleep Specialist or Appropriate Specialist

Patients with significant sleep-related complaints that are not very typical of OSAHS, who have atypical or complicating situations (see Annotation #5, "Atypical or Complicating Symptoms Present?"), or who have symptoms of OSAHS but non-diagnostic sleep tests should be referred to a sleep disorders specialist or an accredited sleep center. Other specialists that may play a role in evaluating such patients include neurologists, otolaryngologists, psychiatrists, or pulmonologists, depending on the symptoms and suspected diagnoses.

7. Sleep Study

Selection of appropriate diagnostic tests, as in all clinical situations, must take into account the estimated pre-test likelihood (prior probability) of the patient having OSAHS, the availability of credible diagnostic tests, and the local expertise in interpreting these complex physiological tests. The diagnosis and treatment of OSAHS should be managed by a physician with proper knowledge in this area. Such physicians may include primary care providers, or specialists such as pulmonologists, neurologists, otolaryngologists or cardiologists.

- The accepted standard test for diagnosis of OSAHS is polysomnography, which is indicated for the diagnosis of all patients suspected of having this disorder. (See the discussion section for more information.) A split night study should be performed where and when possible.
- In patients with a high pretest probability of OSAHS, unattended portable recording for the assessment of obstructive sleep apnea is an acceptable alternative to standard polysomnogram in the following situations: (1) patients with severe clinical symptoms that are indicative of a diagnosis of obstructive sleep apnea and when initiation of treatment is urgent and standard polysomnography is not readily available, (2) for patients unable to be studied in the sleep laboratory, and (3) for follow-up studies when diagnosis has been established by

standard polysomnography and therapy has been initiated. The intent most often is to evaluate the response to therapy.

When the results of the in-home study are diagnostic of OSAHS, an autotitrating positive airway pressure device can be used to titrate an appropriate pressure level except for those patients identified as having atypical or complicating symptoms. (See Annotation #5, "Atypical or Complicating Symptoms Present?")

- Polysomnography is not available in some rural areas. Some patients decline to undergo study in a sleep laboratory. For these and other reasons, some physicians are interested in expanding the use of in-home, unattended, portable recording beyond the three situations listed above. At present the evidence supporting this expansion is limited and at times conflicting, but employment of portable monitoring as a second-best option is not likely to result in harm to patients with a high pretest probability of OSAHS, and may result in less risk than leaving the condition undiagnosed. Portable monitors should not be used in an unattended setting in patients with "Atypical or Complicating Symptoms." (See Annotation #5.) In a patient with suspected OSAHS, a negative study must be followed by a polysomnographic test. The patient and physician must discuss fully the limitations of portable monitoring before employing this strategy.

[Conclusion Grade III: See Conclusion Grading Worksheet - Appendix B - Annotation #7 (Sleep Study) in the original guideline document]

Evidence supporting this recommendation is of classes: C, D, M, R

8. Diagnosis of OSAHS and Determination of Severity?

A diagnosis of OSAHS is confirmed when testing shows that the average number of episodes of apnea and hypopnea per hour of sleep, called the Apnea-Hypopnea Index (AHI), is:

- AHI greater than 15 with either polysomnography or in-home unattended sleep test, or
- AHI greater than 10 using an in-home unattended sleep test when accompanied by symptoms of OSAHS (see discussion section of the original guideline for more information), or
- AHI greater than 5 by polysomnography when accompanied by symptoms of OSAHS, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

The severity of the OSAHS is determined by the most severe rating of three domains, sleepiness, respiratory disturbance (AHI), and gas exchange abnormalities (minimum and mean oxygen saturation). The following can serve as a guide:

- Sleepiness:

        - Mild: Describes sleepiness present only when sedentary or when little attention is required, and may not be present every day. Such sleepiness produces only minor impairment of social or occupational function. As a guide, an Epworth Sleepiness Scale result might be less than 12 (see Annotation Appendix A, "The Epworth Sleepiness Scale" in the original guideline document.)
        - Moderate: Describes daily sleepiness that occurs when minimally active and a moderate degree of attention (e.g., driving, attending meetings or movies). As a guide, an Epworth Sleepiness Scale result might be 13 to 17 (see Annotation Appendix A, "The Epworth Sleepiness Scale" in the original guideline document.)
        - Severe: Describes daily sleepiness during active tasks or tasks that require significant attention. Examples might include driving, conversation, eating, or walking, and usually sleepiness produces marked impairment of social or occupational function. As a guide, an Epworth Sleepiness Scale result might be 18 to 24 (see Annotation Appendix A, "The Epworth Sleepiness Scale" in the original guideline document.)
    - Gas exchange abnormalities:
        - Mild: Mean remains greater than or equal to 90% and minimum oxygen saturation remains greater than or equal to 85%
        - Moderate: Mean oxygen saturation greater than or equal to 90%, with minimum oxygen saturation greater than or equal to 70%
        - Severe: Mean oxygen saturation less than 90%, or minimum oxygen saturation less than 70%.
    - Respiratory Disturbance:
        - Mild: AHI 6 to 20
        - Moderate: AHI 21 to 40
        - Severe: AHI greater than 40

    Evidence supporting this recommendation is of classes: C, D, R

9. Lifestyle Modification

    The following lifestyle modifications can play a significant role in the reduction of severity of sleep apnea symptoms:

    - Weight loss
    - Reduced alcohol consumption, especially before bedtime
    - Body position during sleep (lateral versus supine)
    - Good sleep hygiene
    - Integrate PAP preparation into a bedtime routine and bedroom environment

    Evidence supporting this recommendation is of classes: A, B, C, D, R

Sleep Apnea Treatment Algorithm Annotations

10. Treatment

For patients who have not responded to lifestyle modification, additional treatment options are available and are based on the severity of OSAHS as determined in Annotation #8, "Diagnosis of OSAHS and Determination of Severity?"

11. Mild Obstructive Sleep Apnea Hypopnea Syndrome

There are three options for treatment of mild obstructive sleep apnea hypopnea syndrome (OSAHS). A combination of the treatment options listed below may be necessary to adequately manage the symptoms of OSAHS. Treatment options include:

Oral Appliances

Oral appliances are a recommended treatment for patients with mild OSAHS who have not responded to lifestyle modification. They are a useful treatment alternative for patients who cannot tolerate positive airway pressure devices (described below), though not as effective.

Mandibular repositioning devices are a successful treatment modality for patients with OSAHS with obstruction in the oropharynx and tongue base region.

Tongue retaining devices are helpful for patients with limited or loose natural dentition, temporomandibular disorders and limited mouth opening.

To locate a dentist who can fit oral appliances, consider contacting your local dental society or check the following Internet Web site: www.dentalsleepmed.org.

Evidence supporting this recommendation is of classes: C, D, M, R

Positive Airway Pressure (PAP) Devices

Continuous Positive Airway Pressure (CPAP)

Positive pressure is the most efficacious (next to tracheostomy) for treating OSAHS. CPAP is currently the most commonly used positive airway pressure device. It is a non-invasive/non-pharmacologic method of applying positive pressure to the upper airway via a blower and mask/interface to pneumatically splint the airway thereby preventing collapse. Therapeutic CPAP pressures are generally determined by manual titration during a polysomnogram resulting in a final fixed pressure that eliminates apneic and hypopneic episodes in all stages of sleep and body positions, diminishes sleep fragmentation, snoring, and oxygen desaturations, thereby improving daytime function. Self-titrating CPAP (AutoPAP) can also be utilized for determining an effective CPAP pressure. (See below.)

The success of any positive airway pressure device therapy depends primarily on patient compliance, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the MD and durable medical

equipment (DME) provider, and finally, A.W.A.K.E. (Alert Well And Keeping Energetic) meetings. (See Annotation Appendix B, "Management Tips to Improve Compliance with Therapy" in the original guideline document.) A heated humidifier is strongly suggested in patients with the following circumstances:

- The patient is currently taking drying medications
- Past history of ear nose throat (ENT) surgeries
- Chronic nasal congestion

In all other patients, it may be cost effective and still improve comfort and compliance by ordering CPAP with heated humidity.

Evidence supporting this recommendation is of class: A

AutoPAP (AutoPAP, Self-titrating CPAP, Auto-adjust CPAP)

AutoPAP is a positive pressure apparatus designed to vary pressures to meet the needs of the patient´s sleep-disordered breathing. Pressure changes are determined by monitoring variably a combination of apneas, hypopneas, inspiratory flow limitation, and snoring. Instead of constant maximal pressure, these systems provide the minimal pressure necessary to stabilize the upper airway. The pressures found by these machines generally agree well with those established by skilled technicians.

AutoPAP may be used as an alternative therapy for patients who are intolerant of pressures in conventional CPAP therapy and may be used for an unattended in-home CPAP titration after a positive sleep study or when follow up indicates a need for CPAP pressure change.

The success of any positive airway pressure device therapy depends primarily on patient compliance, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and durable medical equipment provider, and finally, A.W.A.K.E. meetings. (See Annotation Appendix B, "Management Tips to Improve Compliance with Therapy" in the original guideline document.)

Evidence supporting this recommendation is of classes: A, D

Bi-level PAP

Bi-level is a non-invasive respiratory device which delivers different levels of inspiratory (IPAP) and expiratory (EPAP) pressure to a spontaneously breathing patient to keep the upper airway open. By applying a lower pressure during the expiratory phase, the total pressure applied on the airway can then be reduced, thereby achieving closer to normal physiologic breathing.

Bi-level devices have additional flow delivery methods to meet the ventilatory needs of patients with varied respiratory problems, and have been shown therapeutic for OSAHS. Theoretical advantages of bi-level devices include

reducing the work of breathing, lowering of mean treatment pressure, and a more physiologic breathing pattern. These possible advantages make a trial of bi-level devices an appropriate intervention for selected OSAHS patients who do not tolerate continuous pressure or auto-titrating devices. Patients with concurrent or more severe chronic obstructive pulmonary disease or hypoventilation syndromes may also benefit, particularly if they have awake hypercapnia, but very specific criteria must be met to enable Medicare reimbursement. Although selected patients may benefit, the initial use of bi-level devices as initial treatment for OSAHS is not encouraged, since bi-level devices have not been demonstrated to be superior to CPAP in improving compliance, symptom scores, nasal discomfort, or patient complaints regarding therapy. If used, the therapeutic IPAP and EPAP pressures must be achieved by manual titration during an attended polysomnogram and many patients can resume CPAP if re-titration reveals improvement in sleep-disordered breathing with adjustment of pressure.

Bi-level is applied to the patient via nasal mask interface or a full-face interface. Bi-level is indicated not only to correct OSAHS, but may be used as an alternate therapy for patients who are intolerant of conventional CPAP at higher pressures. Bi-level reduces the work of breathing and lowers the mean pressure delivered in the airway.

The success of any positive airway pressure device therapy depends primarily on patient compliance, which can be enhanced by education, proper mask/interface fit, frequent follow-up by the clinician and durable medical equipment provider, and finally, A.W.A.K.E. meetings. (See Annotation Appendix B, "Management Tips to Improve Compliance with Therapy" in the original guideline document.)

Evidence supporting this recommendation is of classes: A, C

Surgical Procedures

The following are surgical procedures available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in mild clinical obstructive sleep apnea syndrome. It may be necessary to correct the anatomical obstruction before prescribing an oral appliance or positive airway pressure device.

Septoplasty - intranasal operation performed to straighten a deviated nasal septum (cause of substantial nasal obstruction)

Nasal polypectomy - intranasal operation to remove nasal polyps

Tonsillectomy - surgical procedure that involves the transoral resection of the pharyngeal tonsils

Turbinoplasty - intranasal operation performed to reduce the size of obstructing nasal turbinates

Uvulopalatopharyngoplasty (UPPP) - the surgical resection of the obstructive portion of the velar musculature of the soft palate and the entire uvula

Evidence supporting this recommendation is of classes: D, R

12. Moderate to Severe Obstructive Sleep Apnea Hypopnea Syndrome

Refer to annotation #11, "Mild Obstructive Sleep Apnea Hypopnea Syndrome"

13. One Month Follow-Up

Evaluation to determine the success and acceptance of treatment is necessary for all patients and will indicate if further evaluation and intervention is necessary. Snoring, sleepiness, and other presenting symptoms which initiated evaluation should be reassessed at this time. If symptoms are persistent, consider a referral to a sleep specialist. The ESS (Epworth Sleepiness Scale) should be repeated at this time, as well as annually.

Positive airway pressure and dental device discomfort can be problematic, contributing to non-compliance. Patient compliance may be enhanced by direct inquiries regarding mask fit, nasal issues, PAP use less than four hours, and attending support/education classes. Follow-up questions are reflected in Annotation Appendix B, "Management Tips to Improve Compliance with Therapy" in the original guideline document.

Evidence supporting this recommendation is of classes: A, C, D, R

15. Refer to Sleep Specialist or Otolaryngologist (ENT) if Appropriate

A sleep specialist evaluation may be indicated to rule out possible causes of unsuccessful treatment unless physical findings of obvious upper airway obstruction are present, in which case a referral to otolaryngologist (ENT) would be indicated. Specific anatomic abnormalities that may predispose to OSAHS include: nasal obstruction, tonsillar hypertrophy, macroglossia, retrognathia, micrognathia, midface hypoplasia, elongated uvular length, hyoid retrusion, large tongue base, redundant pharynx, laryngotracheomalacia, and benign or malignant neoplasms.

The surgical procedures listed below are available for the treatment of symptomatic anatomical obstructions of the upper airway that contribute to or result in clinical obstructive sleep apnea hypopnea syndrome. It may be necessary to correct the anatomical obstruction to increase the effectiveness of an oral appliance or positive airway pressure device.

Septoplasty - intranasal operation performed to straighten a deviated nasal septum (cause of substantial nasal obstruction)

Turbinoplasty - intranasal operation performed to reduce the size of obstructing inferior nasal turbinates

Tracheostomy - creation of an airway through the anterior neck into the upper trachea

Uvulopalatopharyngoplasty (UPPP) - the surgical resection of the obstructive portion of the velar musculature of the soft palate and the entire uvula

Tonsillectomy - surgical procedure that involves the transoral resection of the pharyngeal tonsils

Radiofrequency ablation of the soft palate and tongue base - the administration of microwave radiofrequencies to the treated tissue with a needle-implanted probe. This results in heating of the tissue and secondary scar formation causing a stiffening and reduction of the treated tissue

Hyoid suspension - surgical procedure that results in the hyoid bone being suspended, usually to the mandible, pulling the hyoid bone anteriorly and superiorly

Mandibular advancement, genioglossus advancement, and/or maxillary advancement - procedures to permanently reposition the jaws

Evidence supporting this recommendation is of classes: C, D, R

16. Follow-Up

Continued follow-up should occur no less than annually in the successfully treated patient with OSAHS. Annual follow-up should include all the characteristics of the one-month follow-up. In addition, it is necessary to ensure annually:

- the patient's equipment has been evaluated by qualified personnel
- weight and blood pressure are checked
- if the patient is morbidly obese, consideration of a more aggressive weight-loss program should be pursued
- if there is a significant weight loss or gain, consider adjusting PAP

Follow-up discussions may also include:

- verification patient has current patient education materials
- questions/information regarding travel issues, PAP and hospital visits are addressed
- use of PAP with colds and sinus infections
- long-term expectations
- current mask fit/comfort
- mask cleaning review
- plan to replace mask and supplies every six months
- inquire about drowsy driving issues

Definitions

Classes of Research Reports:

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Class A:

- Randomized, controlled trial

Class B:

- Cohort study

Class C:

- Non-randomized trial with concurrent or historical controls
- Case-control study
- Study of sensitivity and specificity of a diagnostic test
- Population-based descriptive study

Class D:

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- Meta-analysis
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- Decision analysis
- Cost-effectiveness analysis

Class R:

- Consensus statement
- Consensus report
- Narrative review

Class X:

- Medical opinion

Conclusion Grades:

Grade I: The evidence consists of results from studies of strong design for answering the question addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of any significant

doubts about generalizability, bias, and flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

Grade II: The evidence consists of results from studies of strong design for answering the question addressed, but there is some uncertainty attached to the conclusion because of inconsistencies among the results from the studies or because of minor doubts about generalizability, bias, research design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from weaker designs for the question addressed, but the results have been confirmed in separate studies and are consistent with minor exceptions at most.

Grade III: The evidence consists of results from studies of strong design for answering the question addressed, but there is substantial uncertainty attached to the conclusion because of inconsistencies among the results of different studies or because of serious doubts about generalizability, bias, design flaws, or adequacy of sample size. Alternatively, the evidence consists solely of results from a limited number of studies of weak design for answering the question addressed.

Grade Not Assignable: There is no evidence available that directly supports or refutes the conclusion.

CLINICAL ALGORITHM(S)

Detailed and annotated clinical algorithms are provided for:

- Diagnosis of Obstructive Sleep Apnea
- Sleep Apnea Treatment

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guideline contains an annotated bibliography and discussion of the evidence supporting each recommendation. The type of supporting evidence is classified for selected recommendations (see "Major Recommendations").

In addition, key conclusions contained in the Work Group's algorithm are supported by a grading worksheet that summarizes the important studies pertaining to the conclusion. The type and quality of the evidence supporting these key recommendations (i.e., choice among alternative therapeutic approaches) is graded for each study.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Sleep apnea is under-diagnosed. Studies indicate that 2 to 4 percent of adult Americans have the disease and obstructive sleep apnea hypopnea syndrome (OSAHS) is as common as asthma. This guideline was developed to identify those

patients who present to the physician's office at risk for OSAHS. Patients who present for well person exams or for evaluation/follow-up of specific problems can be identified and primary care providers can coordinate the diagnosis and management of OSAHS.

POTENTIAL HARMS

Positive airway pressure and dental device discomfort can be problematic, contributing to non-compliance. (Refer to Annotation Appendix B in the original guideline document for more information.)

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and are not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they form a guideline action group.

In the action groups, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

The following detailed measurement strategies are presented to help close the gap between clinical practice and the guideline recommendations.

Priority Aims and Suggested Measures for Health Care Systems

1. Increase the percentage of patients 18 and older who are diagnosed with obstructive sleep apnea hypopnea syndrome (OSAHS) through a sleep study evaluation.

   Possible measures for this aim.

a. Percentage of patients 18 years of age or older who present for health maintenance exam who are asked about the quality of their sleep and presence of snoring.
b. Percentage of patients presenting with high probability symptoms (see annotation #4 of the original guideline document) or sleep complaints who have been evaluated with a sleep study.
c. Percentage of patients presenting with a diagnosis of hypertension (HTN), coronary artery disease (CAD), or stroke who have been asked about the quality of their sleep.
d. Percentage of patients who are identified at risk for OSAHS and are offered a sleep study.

2. Increase the percentage of patients with OSAHS who have received appropriate treatment according to guideline.

   Possible measures for this aim.

   a. Percentage of patients who have documented follow-up evaluation of sleep study results.
   b. Percentage of patients with a positive sleep study who have been offered treatment.
   c. Percentage of patients receiving OSAHS treatment that have documentation of relief and/or resolution of symptoms.
   d. Percentage of patients with mild OSAHS who have been prescribed a dental appliance, surgery referral, and/or positive airway pressure.

3. Increase the percentage of patients who have documentation of appropriate follow-up.

   Possible measures for this aim.

   a. Percentage of patients with diagnosis of OSAHS who have had a one month follow-up evaluation of treatment.
   b. Percentage of patients diagnosed with OSAHS who have documentation of receiving education on follow-up required for OSAHS patients.

4. Increase patient understanding of the health risk factors related to OSAHS.

   Possible measures for this aim.

   a. Percentage of patients with a high probability pretest for OSAHS with documentation of education on the health risk factors.
   b. Percentage of patients who, after participating in OSAHS program, demonstrate understanding of OSAHS
   c. Percentage of patients with OSAHS attending A.W.A.K.E. (Alert Well And Keeping Energetic) or other education/support group for OSAHS.

At this point in the development of the guideline, there are no specifications written for possible measures listed above. The Institute for Clinical Systems Improvement (ICSI) will seek input from the medical groups on what measures are of most use as they implement the guideline. In a future revision of the guideline, measurement specifications may be included.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2004 May. 53 p. [117 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Apr (revised 2004 May)

GUIDELINE DEVELOPER(S)

Institute for Clinical Systems Improvement - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers, Allina Medical Clinic, Altru Health System, Aspen Medical Group, Avera Health, CentraCare, Columbia Park Medical Group, Community-University Health Care Center, Dakota Clinic, ENT SpecialtyCare, Fairview Health Services, Family HealthServices Minnesota, Family Practice Medical Center, Gateway Family Health Clinic, Gillette Children's Specialty Healthcare, Grand Itasca Clinic and Hospital, Hamm Clinic, HealthEast Care System, HealthPartners Central Minnesota Clinics, HealthPartners Medical Group and Clinics, Hennepin Faculty Associates, Hutchinson Area Health Care, Hutchinson Medical Center, Lakeview Clinic, Mayo Clinic, Mercy Hospital and Health Care Center, MeritCare, Minnesota Gastroenterology, Montevideo Clinic, North Clinic, North Memorial Health Care, North Suburban Family Physicians, NorthPoint Health &: Wellness Center, Northwest Family Physicians, Olmsted Medical Center, Park Nicollet Health Services, Quello Clinic, Ridgeview Medical Center, River Falls Medical Clinic, St. Mary's/Duluth Clinic Health System, St. Paul

Heart Clinic, Sioux Valley Hospitals and Health System, Southside Community Health Services, Stillwater Medical Group, SuperiorHealth Medical Group, University of Minnesota Physicians, Winona Clinic, Winona Health

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GUIDELINE COMMITTEE

Respiratory Steering Committee

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

In the interest of full disclosure, the Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. The reader should not assume that these financial interests will have an adverse impact on the content of the guideline, but they are noted here to fully inform readers. Readers of the guideline may assume that only work group members listed below have potential conflicts of interest to disclose.

Timothy Morgenthaler, MD has received grant support from ResMed.

No other work group members have potential conflicts of interest to disclose.

ICSI's conflict of interest policy and procedures are available for review on ICSI's website at www.icsi.org.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis and treatment of obstructive sleep apnea. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2003 Apr. 53 p.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site.

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org; e-mail: icsi.info@icsi.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was prepared by ECRI on January 28, 2004. This summary was updated by ECRI on July 28, 2004.

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